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Microbial Risk Assessment for the Development of Cleanup Goals

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SCIENCE

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The Public Health Security and Bioterrorism Preparedness and Response Act (the Bioterrorism Act) of 2002, together with Homeland Security Presidential Directives 7, 9, and 10, charge EPA with protecting our nation's critical water infrastructure; monitoring for chemical, biological, and radiological terrorism threats to public health and the environment; and supporting decontamination efforts in the event of an emergency. Our authority for environmental cleanup comes from the NCP.

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The Problems We Face

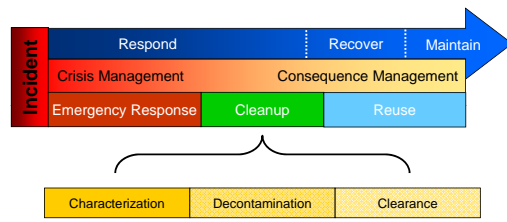
- Protecting against attacks
- Determining that an attack has occurred
- Containing contamination
- Mitigating impacts
- Assessing and communicating risk
- Decontaminating impacted areas
- Disposing of contaminated materials

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Incident Timeline



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Toxicity + Exposure → Risk Characterization

Preparedness Detection Containment Decontamination Disposal

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Risk Assessment

- A process that estimates human health and environmental risks associated with exposures to chemicals present in the environment.
- Toxicity estimates reflect the magnitude of the potential adverse health effects
- Exposure estimates include:
 - Concentration of the chemical in the environment
 - Intake
 - Contact rate, frequency and duration
 - Characteristics of exposed population (e.g., body weight)

Toxicity x Exposure → Risk

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Risk Assessment U.S. EPA Cleanup Goals

- Superfund program
 - Preliminary Remediation Goals (Soil and Water)
- Office of Water
 - Health Advisories
 - Maximum Contaminant Levels
- Office of Air Quality Planning and Standards
 - Reference concentrations
 - Inhalation unit risk

$$\text{Conc.} \times \text{Intake} \times \text{Toxicity} = \text{Risk}$$

$$\text{Risk-based Goal} = \text{Target Conc.} = \frac{\text{Target Risk}}{\text{Intake} \times \text{Toxicity}}$$

Risk Assessment for Homeland Security Challenges

	Chemical	Microbial
Toxicity Assessment	CAS No.	Genetic variants
	Physical state	Life stage
	Toxic	Toxin production
Exposure Assessment	Dose makes the poison	One becomes many
	Enzyme induction	Immunity
	$\mu\text{g}/\text{kg}$, $\mu\text{g}/\text{L}$	cfu/kg , cfu/L
Risk Characterization	Linear pathway, food chain accumulation	Communicable disease
	Toxicity \times Exposure	???

Risk Assessment for Homeland Security Clean-up Decision Making Challenges for Biological Agents

- Limited data available on which to base necessary immediate decisions
 - Unique agents
 - Unique exposure durations
 - Unique exposure situations/sites
- No consensus-based microbial risk assessment methodology
 - Little infectivity/dose response data for agents of interest
 - Few transmission models
- Communication and Transfer
 - Clear and understandable guidance

Risk Assessment for Homeland Security Response Challenges for Biological Agents

- Preparedness
 - What levels must be detected?
 - Will capabilities adequately support health risk-based decisions?
 - Emergency response and recovery
 - When should people be evacuated?
 - When can they return?
- How clean is clean?**

Risk Assessment for Homeland Security Derivation of Cleanup Goals for Biological Agents

- Treatment technologies
 - 6 log kill vs. zero culturable spores
- Environmental background concentrations
 - Endemic populations
 - Disease above background
- Risk-based goals
 - Acceptable risk
 - infective dose and the no-adverse-effect-level

Risk Assessment for Homeland Security Data Needs for Biological Agent Cleanup Goals

- Dose (Infectivity) / Response data
- Exposure models
 - Reaerosolization of particles
 - Human-to-human transmission models
 - Animal reservoirs
- Risk Characterization methods

$$\text{Toxicity (Infectivity)} \times \text{Exposure}$$

$$\int P_i \times C_i$$

$$\sum_i \Phi(a + b \times \ln(\text{DOSE}(t))) \times PE(t)$$



Risk Management
Considerations Impacting Cleanup

- Risk reduction
- Regulatory mandates
- Long-term effectiveness
- Reduction of hazard through treatment
- Short-term effectiveness
- Implementability
- Cost
- State acceptance
- Community acceptance



Risk Assessment for Homeland Security
Challenges for Microbial Risk Assessment

- Will our methods be similar to those we apply to chemical risk?
- Can we define a population 'No-Adverse-Effect-Level'
– is the only good bug a dead bug?
- Should we pursue a risk communication effort to help with public understanding/acceptance of a NOAEL?
- How clean is clean?